In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-0736V
(not to be published)

ROBERTA PEK, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: January 31, 2020 Ruling on Entitlement; Tetanus-Diphtheria-acellular Pertussis (Tdap) Vaccine; Influenza Vaccine; Multiple Sclerosis.

Amy Senerth, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Jennifer Reynaud, U.S. Dep't of Justice, Washington, D.C., for Respondent.

DECISION DENYING ENTITLEMENT[1]

Roberta Pek filed a petition on June 22, 2016, seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program").[2] Petition ("Pet.") at 1 (ECF No. 1). Ms. Pek alleged that she developed multiple sclerosis ("MS") as a result of the influenza ("flu") vaccine she received on October 10, 2014, and the Tetanus, Diphtheria-acellular-pertussis

[1] Although the Decision is not formally designated for publication, it will nevertheless be posted on the Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means that the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its current form. *Id*.

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10–37 (2012) (hereinafter "Vaccine Act" or "the Act"). Individual section references hereafter shall refer to § 300aa of the Act.

("Tdap") vaccine she received on November 14, 2014.[3] *See* Response to Motion to Dismiss at 1, filed May 29, 2019 (ECF No. 45) ("Opp.").

Following the filing of Petitioner's medical records and expert reports, I invited Respondent to move for a ruling on the record seeking dismissal of the claim (*see* Scheduling Order, dated Oct. 29, 2018), and he did so. Motion to Dismiss, filed Apr. 1, 2019 (ECF No. 42) ("Mot."). Shortly thereafter, Petitioner opposed dismissal, offering in support of her claim a supplemental expert report and some items of medical literature. *See generally* Opp.

Having completed my review of the evidentiary record and the parties' filings, I hereby **DENY** Petitioner's request for compensation. As discussed in more detail below, Petitioner has not established that either the flu or Tdap vaccines could jointly cause MS in the manner alleged, nor did she preponderantly prove that the vaccines could do so under the relevant timeframe in which her MS first manifested.

I. Factual Background

A. *History and Vaccination*

Ms. Pek was born on July 11, 1959. Ex. 1 at 1, filed on June 22, 2016 (ECF No. 1-1). Prior to the vaccinations at issue, her medical history was significant for chronic urinary tract infections. Ex. 9 at 15, filed Mar. 30, 2017 (ECF No. 16-3). In addition, from the fall of 2010 to 2013, she attended monthly chiropractic sessions to treat neck and back pain. Ex. 5, filed Sept. 30, 2016 (ECF No. 11-1).

On October 10, 2014, Petitioner received the flu vaccine. Ex. 1 at 1; Ex. 4 at 5, filed Sept. 22, 2016 (ECF No. 8-1). There is no evidence in the medical record of any reaction to this vaccination, or complaints that Petitioner suffered symptoms of any kind within a month of receipt of the vaccine. Just over one month later, on November 14, 2014, Petitioner was seen by Gerren Shinar Perry-Fabrizio, M.D. for a health maintenance visit and treatment of her (pre-vaccination) chronic urinary tract infections. Ex. 4 at 5–10. Following a physical examination that revealed normal results, Petitioner received the Tdap and shingles vaccinations. *Id.* at 7–9. She was also advised to continue taking prophylactic antibiotics as prescribed by her gynecologist. *Id.* at 9.

[3] In her Petition, Ms. Pek initially alleged only that she developed Guillain-Barré syndrome ("GBS") and transverse myelitis ("TM") as a result of the Tdap vaccine she received on November 14, 2014. Pet. at 1. Respondent's expert, Dr. Peter Donofrio, later asserted that Petitioner's condition was more accurately diagnosed as MS. Expert Report of Dr. Donofrio, filed as Ex. A on Mar. 6, 2018 (ECF No. 29-1). Petitioner's later expert, Dr. Lawrence Steinman, subsequently accepted Dr. Donofrio's MS diagnosis, but opined that her illness was the result of *both* the Tdap and flu vaccines. Expert Report of Lawrence Steinman, M.D., filed as Ex. 15 on Aug. 16, 2018 (ECF No. 34-2). This accordingly is the theory that I will resolve (and the one that Petitioner appears to have embraced for purposes of the present ruling on the record).

There is a subsequent two-month gap in the record. Between mid-November 2014 and mid-January 2015, Ms. Pek reported no additional symptoms and did not voice any complaints consistent with her pre-vaccination conditions. Additionally, she did not report any symptoms or express the belief that she was experiencing an adverse reaction related to the vaccines she received. On January 12, 2015, Ms. Pek sought chiropractic treatment for her preexisting neck and back pain at Fulton Family Chiropractic. Ex. 10 at 1, filed Mar. 30, 3017 (ECF No. 16-4). During this visit, she explained that she was generally having difficulty performing tasks of daily living, including sitting, working, getting comfortable, sitting for extended periods of time and extended computer use. *Id.* She also indicated that her symptoms worsened with the cold weather, but she did not identify these problems as having a recent onset. *Id.* Ms. Pek returned to Fulton Family Chiropractic three more times during the month of January complaining of persistent neck and back pain, which she described as dull, aching, moderate, and intermittent, as well as tingling in her legs and gradually worsening numbness. *Id.* at 3, 5, 8–9, 11.

B. *Onset of Suspected Neurologic Symptoms*

On January 28, 2015, Petitioner presented to neurologist Ruwani Gunawardane, M.D., at Maryland Pain & Spine Center, LLC and reported a three-week history of persistent numbness, tingling, and pain below the waist that began on her left buttocks and then progressed to include both lower extremities. Ex. 2 at 2, filed June 22, 2016 (ECF No. 1-5). A physical examination revealed decreased sensation to light touch in the upper extremities, decreased proprioception in both lower extremities, and decreased reflexes in all extremities.[4] *Id.* at 4–5. Ms. Pek informed Dr. Gunawardane that her symptoms were progressing and had started to affect her upper extremities. *Id.* at 5.

Suspecting a demyelinating condition, Dr. Gunawardane ordered an MRI[5] of Ms. Pek's spine. Ex. 2 at 5. The results of the cervical spine MRI conducted on January 28, 2015, showed mild disc degeneration from C4-5 to C6-7 as well as a lesion at the level of C5 consistent with transverse myelitis. Ex. 8 at 1, filed Mar. 30, 2017 (ECF No. 16-2). A few days later, on January 31, 2015, Ms. Pek underwent a brain MRI, which showed non-enhancing periventricular white matter lesions. *Id.* at 4. These findings led to a differential diagnosis of MS, neuromyelitis optica

[4] Dr. Gunawardane's notes abound with typographical errors and inconsistencies. While I certainly considered these records in deciding this matter, it is difficult to give such muddled documentation significant weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy v. Sec'y of Health & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied sub nom. Murphy v. Sullivan*, 506 U.S. 974 (1992)).

[5] Magnetic Resonance Imaging (MRI) is a diagnostic scanning tool that places the patient in a magnetic field rather than exposing him to radiofrequency signals in a traditional x-ray. *Mosby's Manual of Diagnostic and Laboratory Tests* 1106–07 (5th ed. 2014). An MRI provides several benefits over CT scans, such as providing better contrast between normal and pathologic tissue as well as not being obscured by bone artifacts. *Id.* at 1107.

("NMO"), acute disseminated encephalomyelitis, post-vaccinial encephalitis or myelopathies associated with connective tissue or granulomatous disorders. *Id.* Ms. Pek was subsequently prescribed a course of IVIG, to be administered five days each month over a six-month period. Ex. 2 at 5.

C. *TM/MS Diagnosis and Treatment*

On February 5, 2015, Ms. Pek underwent an initial evaluation at Synergy Physical Therapy ("Synergy"). Ex. 3 at 1, filed June 22, 2016 (ECF Nos. 1-6 and 1-7).[6] She reported numbness and tingling throughout her lower extremities—though she indicated that it was the worst in her feet. *Id.* She also described issues with balance, weakness, fatigue, and difficulty walking without fear of falling. *Id.* A physical evaluation showed decreased strength and numbness in both lower extremities. *Id.* at 2. At this visit, Ms. Pek's diagnosis was listed as TM. *Id.* at 3. She was prescribed physical therapy several times weekly for eight weeks. *Id.* at 4. Ms. Pek returned to Dr. Gunawardane on February 9, 2015, at which time she reported 70 percent improvement in the numbness and tingling below her waist. Ex. 2 at 7. She was ordered to undergo a lumbar puncture, the results of which were positive for oligoclonal bands—a finding that Dr. Gunawardane noted as being "suggestive of GBS." *Id.* at 10, 33.

Ms. Pek continued to attend physical therapy several days a week throughout February 2015. Ex. 3 at 7–15. During these visits, Ms. Pek reported that her symptoms, though persistent, were improving, and she was steadily regaining strength, energy, and balance. *Id*. On February 27, 2015, Ms. Pek saw Dr. Gunawardane for a follow-up appointment. Ex. 2 at 26. After a review of Ms. Pek's history as well as a physical examination, Dr. Gunawardane ordered her to undergo an NMO antibody test. *Id.* He additionally noted that "IVIG is medically necessary 5 days for the acute relapse she failed solu Medrol 1 gm x 5 days still has residual symptom[]s pati[ent] will benefit from Acthar 80 unites qd x 5 days." *Id.* The NMO antibody test was performed on February 27, 2015, but the results of the test were negative. *Id.* at 28.

Ms. Pek continued regularly attending physical therapy at Synergy throughout March 2015. During this time, she reported improvements in her strength, energy, and balance, and that she felt less numbness and tingling each day. Ex. 3 at 16, 22–29. Physical evaluations also revealed that she had increased strength in her lower extremities—though there were still deficits. *Id.* at 17. On March 13, 2015, Ms. Pek again returned to Dr. Gunawardane. Ex. 2 at 30. While discussing Ms. Pek's medical history, Dr. Gunawardane documented the onset of Ms. Pek's condition as January 15, 2015. *Id.* The record from this visit reports that Ms. Pek was still experiencing persistent and worsening pain, numbness, tingling, localized weakness, and temperature sensitivity in all extremities. *Id.* She explained that both cold temperatures and stress exacerbated her symptoms. *Id.*

[6] Exhibit 3 was filed as two consecutively-paginated volumes.

During a physical examination, Dr. Gunawardane noted that almost all of Ms. Pek's reflexes were absent. Ex. 2 at 33. The differential diagnosis at the conclusion of this visit included GBS, MS, TM, and disturbance of skin sensation. *Id.* Ms. Pek was not proving responsive to steroid treatments, and her lumbar puncture was positive for oligoclonal bands, which Dr. Gunawardane again deemed "suggestive of GBS." *Id.* At the conclusion of the appointment, Dr. Gunawardane provided an updated treatment plan for Ms. Pek, which included "IVIG 40 gm qd x 5 days each month is 6 months is medically necessary for GBS." *Id.* at 34.

At Ms. Pek's follow-up appointment on April 3, 2015, Dr. Gunawardane noted that her lower extremity weakness and numbness showed improvement following IVIG treatment. *Id.* at 38. The next day, Ms. Pek returned to Synergy and reported that she continued to notice improvements in both her strength and balance, an assessment echoed by her treaters. Ex. 3 at 31, 33–34. As a result, on April 17, 2015, she was discharged from physical therapy. *Id.* at 44. At the time, she reported improved strength and balance, and she was able to perform most activities of daily living. *Id.*

Over six months later, Ms. Pek followed up with Dr. Gunawardane on November 20, 2015. Ex. 2 at 45–49. After a review of Ms. Pek's symptoms and medical history, Dr. Gunawardane provided a differential diagnosis including GBS, TM, MS, and disturbance of skin sensation. Ex. 2 at 48–49. He additionally noted that Ms. Pek was not experiencing recurrent symptoms and that her leg weakness had improved with IVIG. *Id.* at 48. He specifically discouraged Ms. Pek from receiving future flu vaccinations "due to GBS." *Id.* at 49.

D. *Subsequent Follow-Up Treatment*

On November 25 and 28, 2015, Ms. Pek underwent new MRI scans of her brain and cervical spine respectively. Ex. 8 at 11, 13–14. The results of the repeat brain MRI showed two new lesions in the periventricular white matter of her brain, and the repeat MRI of her cervical spine showed an enhancing lesion extending from C4-C6, which was consistent with her initial MRI conducted on January 28, 2015. *Id.* A third MRI of Ms. Pek's brain conducted on November 23, 2016, showed that the periventricular lesions remained stable. *Id.* at 16.

Ms. Pek continued to treat with Dr. Gunawardane into the spring of 2016. Ex. 2 at 45–64. During this time, she did not experience any recurrent symptoms, and Dr. Gunawardane noted that there were no other signs of MS. *Id.* at 52. Ms. Pek now reported that she was able to walk, and the records suggest that her symptoms had dissipated—though Dr. Gunawardane's disorganized and contradictory documentation makes it difficult to establish this point with any kind of certainty. *Id.* at 54–58.

II. Expert Reports

A. *Petitioner's Expert: Dr. Lawrence Steinman, M.D.*

Dr. Steinman submitted two expert reports on behalf of Petitioner. Expert Report of Lawrence Steinman, M.D., filed as Ex. 15 on Aug. 16, 2018 (ECF No. 34-2) ("Steinman Rep."); Supplemental Expert Report of Lawrence Steinman, M.D., filed as Ex. 16 on May 29, 2019 (ECF No. 44-2) ("Steinman Supp. Rep."). Dr. Steinman opines that Ms. Pek developed MS after receiving the influenza ("flu") vaccination on October 10, 2014, with the Tdap vaccine she subsequently received playing a contributory role.[7] Steinman Rep. at 1. He also opines that the onset of Ms. Pek's symptoms—occurring eight weeks following the Tdap vaccine's administration—and hence twelve weeks after receiving the flu vaccine—was medically reasonable.

As shown in his CV, Dr. Steinman received his B.A. from Dartmouth College and his M.D. from Harvard Medical School. Ex. 15 at 1, filed Sept. 4, 2018 (ECF No. 35-1) ("Steinman CV"). He then completed residencies in neurology and pediatrics at Stanford University. *Id.* He has worked as a professor of neurology and pediatrics at Stanford for the past thirty-eight years. *Id.* Dr. Steinman has also published over five hundred peer-reviewed publications on neurology and autoimmune disease. Steinman CV at 5–45. He has special expertise in study of the pertussis toxin, as several of his published articles specifically pertain to the interaction of pertussis and the immune system (although he has not written on the topic in many years), and he patented certain work related to the development of the acellular pertussis vaccine. *Id.* at 2–45.

In his reports, Dr. Steinman began by opining that the flu vaccine Petitioner received on October 10, 2014, could trigger an immune response to myelin proteins in the nerves sufficient to stimulate injury. Steinman Rep. at 5–6; Steinman Supp. Rep. at 15–16. As he asserted, "immune responses to myelin proteins are detected in MS patients," thus corroborating the theory that an immunologic cross-reaction process could occur against self-myelin. Steinman Rep. at 6. This process, Dr. Steinman explained, was the result of molecular mimicry, whereby foreign antigens presenting to the immune system would stimulate an immune attack not just against the antigen but against self-amino acid sequences homologous to the presenting antigen and known to be associated with a disease process—here, structures on the nerve myelin. Steinman Rep. at 7–17; R. Fujinami et al., *Molecular Mimicry, Bystander Activation, or Viral Persistence: Infections and Autoimmune Disease*, 19 Clinical Microbiology Rev. 80, 80–81 (2006), filed as Ex. 15.12 on Sept. 4, 2018 (ECF No. 35-12).

[7] Though Dr. Steinman discusses all three vaccines Ms. Pek received (flu, Tdap, and shingles), he maintains that only the October 10, 2014 flu vaccine and the November 14, 2014 Tdap vaccine "were the substantial factors in triggering MS in the Petitioner," and indicates that he did not consider the potentially contributory role of the shingles vaccine because it is not covered by the Vaccine Program. Steinman Rep. at 1.

In support of his theory, Dr. Steinman noted that specific components of the 2014-15 flu vaccine that Petitioner received can be demonstrated to possess significant homology to amino acid sequences contained in the myelin proteins, which in turn increased the likelihood of cross-reactivity and the initiation of an autoimmune process. Steinman Rep. at 8–11; Steinman Supp. Rep. at 2–11; T. Derfuss et al., *Contactin-2/TAG-1-directed Autoimmunity is Identified in Multiple Sclerosis Patients and Mediates Gray Matter Pathology in Animals*, 106 PNAS 8302, 8302 (2009), filed as Ex. 15.13 on Sept. 4, 2018 (ECF No. 35-13). He reached this determination via a "BLAST" search, which was conducted by searching an online database for homologous amino acid sequences contained in the flu vaccine administered to Petitioner and the sequences commonly associated with myelination. *See* Steinmann Rep. at 8, 11. Thus, the "seeds" for an autoimmune reaction had been planted with Petitioner's receipt of the flu vaccine.

Second, this putative autoimmune process was assisted by the Tdap vaccine's alum adjuvant and its immune-stimulative effect. Steinman Rep. at 16; Steinman Supp. Rep. at 11. Petitioner's immune response to the flu vaccine was already "vigorous at approximately a month to five weeks after the [flu] vaccine, when the Tdap was given." Steinman Rep. at 16. Then, alum included in the Tdap vaccine as an adjuvant (intended to promote an immune response) induces the production of a particular cytokine, interleukin-1β ("IL-1β"),[8] which he maintained plays a "critical role" in the pathogenesis of MS. Steinman Rep. at 16; Steinman Supp. Rep. at 11; S. Hauser, *Cytokine Accumulations in CSF of Multiple Sclerosis Patients: Frequent Detection of Interleukin-1 and Tumor Necrosis Factor but Not Interleukin-6*, 40 Neurology 1735, 1735 (1990), filed as Ex. 15.22 on Sept. 4, 2018 (ECF No. 35-22) ("Hauser"). But, although Hauser (an article published thirty years ago) did measure the amounts of this cytokine found in individuals with MS, and did propose ways in which the disease might be advanced as a result of its presence, the article does not assert that this cytokine is a *primary* driver of disease (and might instead be produced in *response* to disease). Hauser, *supra*, at 1737–38. Nevertheless, Dr. Steinman proposed that a purported triggering of IL-1β cytokines induced by alum in the Tdap vaccine was enough to advance Petitioner's disease process (although he offered no literature discussing the putative link between the two arguably complimentary processes). *Id.*; Steinman Supp. Rep. at 15–16.

Dr. Steinman's reports went on to consider the timeframe in which Petitioner's MS manifested, in comparison to her vaccination dates. In his first report, Dr. Steinman accepted that Petitioner's onset of symptoms began three weeks prior to her visit to Dr. Gunawardane on January 28, 2015—putting onset on or about January 7, 2015. Based on this timeline, Dr. Steinman opined that "[t]he onset of symptoms of multiple sclerosis thus began 84 days after the [flu] vaccine, and

[8] IL-1β is a type of cytokine that mediates antigen-specific responses through direct activation of lymphocytes. Hauser, *supra*, at 1735.

49 days after the immunization with Tdap . . . ."[9] Steinman Rep. at 17. This, Dr. Steinman concluded, established a medically reasonable proximate temporal relationship between the vaccines Petitioner received and the MS she subsequently developed (although his report said little as to why this was so, and provided almost no supporting citation to back up the determination). *Id.* at 18.

In his second report, Dr. Steinman expounded upon the third *Althen* prong, discussing medical literature he felt supported his position. He maintained that Petitioner's onset of MS symptoms forty-nine days after receiving the Tdap vaccine was reasonable, referencing research that he said stood for the proposition that immune responses to a molecular mimic can occur up to six months after the mimic's introduction. Steinman Supp. Rep. at 14–15; B. Bielekova et al., *Encephalitogenic Potential of the Myelin Basic Protein Peptide (Amino Acids 83-99) in Multiple Sclerosis: Results of a Phase II Clinical Trial with an Altered Peptide Ligand*, 6 Nature Medicine 1167, 1168 (2000), filed as Ex. 16.3 on May 29, 2019 (ECF No. 44-5) ("Bielekova"). In Bielekova, researchers sought to identify potential immune-suppressive treatments for MS, relying on the theory that MS (understood to be an autoimmune disease) is mediated by a T cell that is "myelin-specific," and hence blocking certain T cell responses might be therapeutic. Bielekova, *supra*, at 1167. Its authors accordingly treated 24 patients previously diagnosed with relapsing-remitting MS with a molecular mimic of the protein responsible for myelination,[10] administering the protein mimic on a weekly basis over a nine-month period. *Id.* at 1167, 1173. Only one subject completed the entire treatment, however, and several experienced lesion exacerbations that caused the researchers to reduce trial dosage (although only one subject's relapse was considered to be treatment-related). *Id.* at 1167–68, 1173.

Bielekova observed overall that "[t]he selected dosing regimen was poorly tolerated" in the subject patients, and "did not generally improve or worsen disease," although the study did find that some T cells thought necessary to suppress aberrant immune activity characteristic of MS were expanded in number through administration of the mimic protein. *Id.* at 1172–73. Nevertheless, its authors deemed their ultimate findings "disappointing," adding that "there is little doubt that the administration of [the protein MBP mimic] *activated* disease-mediating T cells." *Id.*

[9] The parties do not dispute the dates of vaccination relevant to this case. Mot. at 10. They also agree that the onset of Petitioner's symptoms began three weeks prior to January 28, 2015—putting onset on or around January 7, 2015. *Id.* Respondent has pointed out (and I have confirmed) that onset would therefore have in fact occurred *eighty-nine* days after Petitioner's receipt of the flu vaccine and *fifty-four* days after receipt of the Tdap vaccine, rather than the eighty-four and forty-nine days calculated by Dr. Steinman. *Id.* I also note that even after Respondent brought this miscalculation to Dr. Steinman's attention, he continued to rely on the incorrect timing in concluding that Petitioner's onset occurred within a medically acceptable timeframe. Steinman Supp. Rep. at 13–15. This modest error does not, however, drive my determination—since I find that *either* eighty-four or eighty-nine days is still too long after vaccination to be medically reasonable under the circumstances.

[10] Myelination is the process by which the body produces a fatty substance that coils around nerve cells providing a protective sheath and electrical insulator. *Dorland's Illustrated Medical Dictionary* 1218 (32 ed. 2012) (hereinafter "*Dorland's*").

at 1173 (emphasis added).

Bielekova does not appear at first glance to be particularly helpful to Petitioner—yet Dr. Steinman cites it in his supplemental report and highlights its importance. He did so based upon his view that Bielekova reported prolonged immune response times—up to six months in one patient—after introduction of the molecular mimic. Steinman Supp. Rep. at 14, *citing* Bielekova, *supra*, at 1168 (Figure 1(c)). This suggested to Dr. Steinman that an individual exposed to an antigen with the potential to instigate an autoimmune cross-reaction could experience an immunological response up to six months later as well. *See* Steinman Supp. Rep. at 15; Bielekova, *supra*, at 1167–68. He does not mention, however, the fact that (unlike the Petitioner) Bielekova's subjects received the immune-stimulating antigen not one time, but on a *weekly* or *monthly* basis. Indeed, the cited six-month time period (which pertains only to three of the study's total subjects) includes a timeline referencing "months on trial," rather than time *after* a final dose of the mimic. Bielekova, *supra*, at 1168 (Figure 1(c)). Accordingly, Bielekova says far less about a potentially lengthy timeframe for post-vaccination autoimmune responses than Dr. Steinman purports.

B. *Respondent's Expert: Dr. Peter Donofrio, M.D.*

Dr. Donofrio served as Respondent's expert in this matter and provided a single expert report. Report, filed as Ex. A on Mar. 6, 2018 (ECF No. 29-1) ("Donofrio Rep."). In his report (which addressed only the opinions set forth in the reports of Petitioner's initial expert), Dr. Donofrio opined that the most accurate diagnosis for Petitioner's condition was MS. *Id.* at 6. But he also concluded that existing medical literature does not support a causal connection between the Tdap vaccine and MS. *Id.*

Dr. Donofrio is a professor of neurology at Vanderbilt University Medical Center and serves as chief of the Neuromuscular Section and director of the EMG lab. *Id.* at 1. He is board certified in neurology, internal medicine, as well as EMG and neuromuscular disorders. *Id.* As a practicing neurologist for over thirty-eight years, Dr. Donofrio has treated hundreds of patients suffering from GBS, chronic inflammatory demyelinating polyneuropathy ("CIDP"), TM, MS, and peripheral neuropathy. *Id.* at 1, 5. He has published work related to GBS, CIDP, and other neuropathies, and he is familiar with the medical literature relating to vaccine-related neurologic disorders. *Id.* at 1.

In his report, Dr. Donofrio emphasized that Petitioner's illness was best characterized as MS. *Id.* at 6. While he acknowledges the range of diagnoses proposed by Petitioner's treating physician (including GBS, TM, CIDP, and disturbance of the skin), his own review of the medical record led him to conclude that MS more accurately accounted for Petitioner's symptoms, and was better supported by her diagnostic test results as well. *Id.*; *see also* C. Polman et al., *Diagnostic Criteria for Multiple Sclerosis: 2010 Revisions to the McDonald Criteria*, 69 Annals Neurology 292, 294 (2011), filed as Ex. A, Tab 2 on Mar. 6, 2018 (ECF No. 29-3) ("McDonald Criteria").

Dr. Donofrio articulated that to be diagnosed with MS, a patient must exhibit lesions within the central nervous system ("CNS") that are disseminated in time and space. Donofrio Rep. at 6; McDonald Criteria, *supra*, at 292. Dissemination in space is demonstrated by lesions located in at least two of four specific CNS locations—the periventricular, juxtacortical, or infratentorial areas of the brain,[11] or the spinal cord. McDonald Criteria, *supra*, at 294. Dissemination in time is demonstrated by new enhancing lesions in a follow-up MRI or by the simultaneous presence of asymptomatic enhancing and non-enhancing lesions at the same time. *Id.* In addition, and although not required, the presence of oligoclonal bands in CSF studies also supports a diagnosis of MS and can help differentiate it from other demyelinating conditions impacting the CNS. *Id.* at 296.

Dr. Donofrio opined that Petitioner's clinical presentation and diagnostic testing meets the McDonald diagnostic criteria for MS. Donofrio Rep. at 6. Petitioner's January 28, 2015 MRI showed an enhancing lesion in her cervical spinal cord. Ex. 8 at 1. A brain MRI conducted on January 31, 2015, demonstrated additional lesions in the posterior periventricular region as well as in the bilateral subcortical white matter of the brain. *Id.* at 4. Later, on November 25, 2015, a repeat MRI showed new, non-enhancing lesions in the frontal periventricular white matter of the brain in addition to the previously documented periventricular and subcortical lesions. *Id.* at 11. Based on such evidence, Dr. Donofrio concluded that the course of Petitioner's disease process as demonstrated by the development of new lesions in multiple locations of the CNS at various points in time met each of the diagnostic criteria for MS. Donofrio Rep. at 6. He further bulwarked this opinion by citing to Petitioner's CSF study,[12] which was positive for oligoclonal bands. *Id.* at 9; Ex. 2 at 10, 33.

Having concluded that Petitioner's proper diagnosis is MS, Dr. Donofrio went on to explain that existing medical literature does not support a causal relationship between components of the Tdap vaccine and MS. Donofrio Rep. at 6 (citing Institute of Medicine, *Adverse Effects of Vaccines: Evidence and Causality*, 553 (Kathleen Stratton et al. eds., 2012), filed as Ex. A, Tab 3 on Mar. 6, 2018 (ECF No. 29-4) ("IOM Report"). The IOM Report states that there was inadequate evidence "to accept or reject a causal relationship between diphtheria toxoid, tetanus toxoid, or acellular pertussis-containing vaccines and the onset of MS in adults." IOM Report, *supra*, at 553.

Regarding the third *Althen* prong, Dr. Donofrio opined that the onset of Petitioner's symptoms was too far removed from the date of vaccination to support a causal relationship. Donofrio Rep. at 6. By his estimation, Petitioner first began experiencing symptoms no sooner

[11] Periventricular describes the area near or around the brain's ventricles—cavities within the brain that are filled with cerebrospinal fluid ("CSF"). *Dorland's* at 1141, 2047. The juxtacortical region of the brain is the area adjoining the cerebral cortex. *Id.* at 421, 975. The infratentorial area of the brain is the area below the outermost membrane covering of the brain. *Id.* at 938, 1794, 1883.

[12] While Dr. Gunawardane references a CSF study and the results of that study in the medical record, Petitioner has not submitted any records documenting the lumbar puncture or supporting documentation with the results of the CSF study.

than fifty-two days after receiving the Tdap vaccination. *Id.* This, he explained, was far beyond the timeframe for onset of even widely-accepted autoimmune demyelinating conditions, referencing in support a 1984 study which found that a causal connection between the 1976-1977 flu vaccine and GBS could not be established after six weeks (forty-two days) following vaccination. A. Langmuir et al., *An Epidemiologic and Clinical Evaluation of Guillain-Barré Syndrome Reported in Association with the Administration of Swine Influenza Vaccines*, 119 Am. J. Epidemiology 841, 841, 855 (1984), filed as Ex. A, Tab 1 on Mar. 6, 2018 (ECF No. 29-2) ("Langmuir"). The timeframe is this case was significantly longer, even if Tdap were solely deemed causal.

C. *Additional Expert Reports: Omid Akbari, PhD*

Prior to the submission of Drs. Steinman and Donofrio's expert reports, Petitioner filed two reports from Dr. Omid Akbari, PhD.[13] *See generally* Expert Report of Omid Akbari, Ph.D., filed as Ex. 11 on May 30, 2017 (ECF No. 18) ("Akbari First Rep."); Supplemental Expert Report – Omid Akbari, filed as Ex. 13 on Sept. 11, 2017 (ECF No. 27) ("Akbari Supp. Rep."). In them, Dr. Akbari opined that Ms. Pek developed GBS or CIDP following her November 14, 2014 Tdap and shingles vaccinations. Akbari First Rep. at 1; Akbari Supp. Rep. at 2.[14] However, after Dr. Donofrio expressed the opinion that Petitioner suffered only from MS and not a peripheral neuropathy like GBS, Petitioner appears to have abandoned the diagnoses and theories proposed by Dr. Akbari, and instead now relies solely on the opinions expressed by Dr. Steinman, which accept MS as the proper diagnosis in this case. *See generally* Opp. (discussing only those opinions and conclusions contained within Dr. Steinman's reports). For this reason, the Decision will not further address the opinions and theories expressed in the reports submitted by Dr. Akbari.[15]

[13] Dr. Akbari is a professor of allergy and immunology at Keck School of Medicine at the University of Southern California. Akbari First Rep. at 1; See also Omid Akbari CV, filed as Ex. 12 on May 30, 2017 (ECF No. 18-2) ("Akbari CV"). He received his bachelor and master's degrees from University College London. Akbari CV at 1. He then received a Ph.D. in cellular and molecular immunology from the National Institute for Medical Research in London before completing a postdoctoral fellowship at Stanford University. Id. He has and continues to serve on the editorial board of several journals, and he has numerous publications in the area of immunology and allergy research. Id. at 4–5, 9–13. Dr. Akbari is not a medical doctor, and therefore he does not diagnose or treat patients with neurological diseases in a clinical setting.

[14] Dr. Akbari specifically opined that the theory of molecular mimicry causally linked Ms. Pek's GBS and CIDP to the Tdap and shingles vaccines she received on November 14, 2014. Akbari First Rep. at 13–14. He further emphasized his view that Ms. Pek was more likely to develop an autoimmune disorder like GBS or CIDP because she received multiple vaccines simultaneously. *Id.* at 13. Based on a review of Ms. Pek's medical records, he also concluded that the onset of her symptoms following vaccination occurred within a reasonable timeframe. *Id.* Dr. Akbari later narrowed his conclusions in a supplemental report by espousing the opinion that the Tdap vaccine alone could induce molecular mimicry leading to the development of GBS and CIDP. Akbari Supp. Rep. at 2. In the same supplemental report, Dr. Akbari defined the timeframe during which he believed Ms. Pek first began experiencing GBS and/or CIDP symptoms. *Id.* Dr. Akbari's proposed timeline dated Ms. Pek's onset at three weeks following vaccine administration—putting onset on or about December 5, 2014. *Id.*

[15] Had Petitioner opted to rely solely on Dr. Akbari's opinion, I would dismiss the claim based on the determination that the injury she suffered (MS) was more likely than not different from what that opinion proposed. *See generally*

III. Procedural Background

After this case was initiated and following the filing of pertinent medical records, Respondent filed his Rule 4(c) Report on January 6, 2017, contesting Ms. Pek's entitlement to damages. Respondent's Report, filed Jan. 6, 2017 (ECF No. 13). I subsequently ordered the parties to file expert reports in support of their respective positions, and they did so as set forth above. Thereafter, on October 10, 2018, Respondent filed a Motion for Order to Show Cause, to which Petitioner filed her Response on October 24, 2018. Motion for Order to Show Cause, filed Oct. 10, 2018 (ECF No. 39); Response to Motion for Order to Show Cause, filed Oct. 24, 2018 (ECF No. 40). I then instructed the parties to brief the issues of this case and to provide supplemental expert reports (if necessary) for my consideration. Scheduling Order dated Oct. 29, 2018. After several extensions of time, Respondent filed a Motion to Dismiss on the Record. Mot. Petitioner responded and provided a supplemental expert report from Dr. Steinman on May 29, 2019. Steinman Supp. Rep; Opp. The matter is now ripe for resolution.

IV. Parties' Respective Arguments

A. *Respondent's Motion*

Respondent argues that the theory of causation offered by Petitioner is inherently unreliable as applied to the facts of this case. Mot. at 6. He maintains that Dr. Steinman's use of database searches to locate homologies between vaccine components and myelin proteins does not amount to substantive evidence that the identified homologies would result in a disease process. *Id.* at 7. Further, he emphasizes Dr. Steinman's own acknowledgement of his theory's limited scope, when he reported that cross-reactivity may induce autoimmunity without simultaneously causing disease. *Id.* at 7 (citing Steinman Rep. at 7, 16). In effect, Respondent maintains, all Dr. Steinman has done is invoke the term "molecular mimicry" for his theory—an act which has consistently been found unpersuasive in establishing causation in the Vaccine Program. Mot. at 7, 9; *see Heddens v. Sec'y of Health & Human Servs.*, No. 15-734V, 2018 WL 5726991 at *3 (Fed. Cl. Spec. Mstr. Oct. 5, 2018) (quoting *Caves v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 119, 135 (2011), *mot. for rev. denied*, 143 Fed. Cl. 193 (2019).

Similarly, Respondent argues that Dr. Steinman's opinion is not enough to establish a causal relationship between the vaccines Petitioner received and her subsequent neurologic injury, in the absence of treater support for an association. Mot. at 9. He notes that none of Petitioner's treating physicians identified, or even insinuated, any connection between the flu or Tdap vaccines

Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339 (Fed. Cir. 2010) (affirming a special master's denial of entitlement when petitioner failed to provide expert testimony supporting a causal relationship between vaccines and petitioner's injury).

that she received and her subsequent development of MS.[16] *Id.* Respondent posits that the record does not support a finding that the flu and Tdap vaccines acting in concert *could* result in MS, eighty-nine days after the flu vaccination and fifty-four days after the Tdap vaccination. *Id.* at 10. In support, Respondent notes that as of April 1, 2019, when he filed the present motion, only two articles relevant to the issue of timing had been filed. *See* Langmuir, *supra*, at 841; L. Schonberger et al., *Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976-1977*, 110 Am. J. Epidemiology 105, 105 (1979), filed as Ex. 15-24 on Sept. 4, 2018 (ECF No. 35-24). But both articles were dismissed by Dr. Steinman as inapplicable because they studied the 1976 flu vaccine, which according to Dr. Steinman is "quite different" from the flu vaccine administered to Petitioner, and the studies focused on GBS, not MS. *Id.* at 12 (citing Steinman Rep. at 17). At the time the instant motion was filed, no other items of literature had been filed to support Petitioner's showing on the third *Althen* prong. Therefore, Respondent argues that Dr. Steinman's contention that the onset of Petitioner's symptoms fell within a medically reasonable timeframe is unsupported and is insufficient to meet Petitioner's burden in this case. Mot. at 12.

B. *Petitioner's Opposition*

Petitioner maintains that molecular mimicry reliably establishes a causal relationship between the vaccines she received and her subsequent injury. Opp. at 1. In support of her argument, Petitioner argues that Dr. Steinman's theory was sufficiently detailed and specific to the record. *Id.* at 3. Specifically, she emphasizes that Dr. Steinman, rather than merely invoking the concept of molecular mimicry, reviewed specific homologies present between the flu vaccine that she received and myelin proteins. *Id.* Dr. Steinman also identified a proposed specific mechanism through which the Tdap vaccine would stimulate IL-1β—a critical cytokine in the pathogenesis of MS. *Id.*

Because each mechanism cited by Dr. Steinman is independently supported by the medical literature, Petitioner argues that both mechanisms acting together are sufficient to preponderantly establish a causal link between the vaccines she received and her MS, and thus satisfy the "can cause" *Althen* prong. Under this causal chain of events, the flu vaccination Petitioner received initiated an immune reaction and subsequently produced autoimmunity because of the overlapping amino acid sequences between the vaccine and myelin proteins. *Id.* at 4. She then experienced dual stimulation leading to neuroinflammation when she received the Tdap vaccine. *Id.* Petitioner similarly utilizes this opinion by Dr. Steinman along with the timeframe in which Petitioner first

[16] At most, on January 28, 2015, Dr. Gunawardane noted that Petitioner had received the shingles vaccine prior to the onset of her symptoms. Ex. 2 at 2. Later, on November 20, 2015, he discouraged Petitioner from getting the flu shot in the future "due to GBS," though the parties agree the Ms. Pek's condition is not GBS, but rather MS. *Id.* at 49. Nowhere in the record does Dr. Gunawardane discuss the possible role the flu or Tdap vaccinations—the only vaccinations for which Petitioner could possibly be entitled to compensation—may have had in her development of MS. *See generally* Ex. 2; Ex. 8.

developed symptoms of MS to satisfy the second *Althen* prong. *Id.* at 4–5; *see also* Bielekova, *supra*, at 1167–68.

Regarding the third *Althen* prong, Petitioner again relies on Dr. Steinman's opinion that an onset of MS symptoms eighty-four days after receipt of the flu vaccine and forty-nine days after receipt of the Tdap vaccine is a medically acceptable timeframe in which a causal relationship between the vaccines and Petitioner's MS can be inferred. Opp. at 5–6. Petitioner argues that the immune response to myelin that was induced by the flu vaccine could persist for up to five weeks after vaccination. *Id.* at 6. This would overlap with the date of her Tdap vaccination. *Id.* The dual stimulation of both the flu and Tdap vaccines working together in this form was then sufficient to trigger her MS. *Id.*

V. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[17] In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed.

[17] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, many decisions of the Court of Federal Claims and Federal Circuit have emphasized that petitioners need only establish a causation theory's biological plausibility (and thus need not do so with preponderant proof). *Tarsell v. United States,* 133 Fed. Cl. 782, 792–93 (2017) (special master committed legal error by requiring petitioner to establish first *Althen* prong by preponderance; that standard applied only to second prong and petitioner's overall burden); *see also Contreras,* 121 Fed. Cl. at 245; *Andreu*, 569 F.3d at 1375. At the same time, there is contrary authority from the Federal Circuit suggesting that the same preponderance standard used overall in evaluating a claimant's success in a Vaccine Act claim is also applied specifically to the first *Althen* prong. *See, e.g.*, *Broekelschen*, 618 F.3d at 1350 (affirming special master's determination that expert "had not provided a 'reliable

medical or scientific explanation' *sufficient to prove by a preponderance of the evidence a medical theory* linking the [relevant vaccine to relevant injury].") (emphasis added). Regardless, one thing remains: petitioners always have the ultimate burden of establishing their Vaccine Act claim *overall* with preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell*, 133 Fed. Cl. at 793 (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard)[18].

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

[18] Although decisions like *Contreras* suggest that the burden of proof required to satisfy the first *Althen* prong is less stringent than the other two, there is ample contrary authority for the more straightforward proposition that when considering the first prong, the same preponderance standard used overall is also applied when evaluating if a reliable and plausible causal theory has been established. *Broekelschen*, 618 F.3d at 1350.

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd sub nom. Rickett v. Sec'y of Health & Human Servs*., 468 F. Appx. 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez*

v. Sec'y of Health & Human Servs., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie*, 2005 WL 6117475, at *20. Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy*, 23 Cl. Ct. at 733 (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

There are, however, situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("'[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent'") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *Lalonde v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen*, 618 F.3d at 1347 (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for rev. denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. Appx. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program

cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

Expert opinions based on unsupported facts may be given relatively little weight. *See Dobrydnev v. Sec'y of Health & Human Servs.*, 556 F. Appx. 976, 992–93 (Fed. Cir. 2014) ("[a] doctor's conclusion is only as good as the facts upon which it is based") (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("[w]hen an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion")). Expert opinions that fail to address or are at odds with contemporaneous medical records may therefore be less persuasive than those which correspond to such records. *See Gerami v. Sec'y of Health & Human Servs.*, No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013), *aff'd*, 127 Fed. Cl. 299 (2014).

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not every filed item factors into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Human Servs.,* 527 F. Appx. 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Resolution of Case Via Ruling on Record*

I have opted to resolve this matter on the papers, rather than by holding a hearing. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *See Kreizenbeck v. Sec'y of Health & Human Servs.*, No. 08-209V, slip op. at 8 (Fed. Cir. Jan. 6, 2020); *Hooker v. Sec'y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences

of the parties.[19] *Hovey v. Sec'y of Health & Human Servs*., 38 Fed. Cl. 397, 402–03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy* 23 Cl. Ct. at 730–31.

ANALYSIS

I. Petitioner Has Not Carried her Burden under the *Althen* Test

There is no dispute in this case about the vaccines in question or the date Ms. Pek likely experienced onset (around January 7, 2015). In addition, it appears Petitioner accepts Dr. Donofrio's contention that she suffered from MS. *See* Steinmann Rep. at 5; *see generally* Opp. Thus, the matter to be resolved is whether the flu and/or Tdap vaccines could cause MS in the joint manner proposed, whether they did so here, and whether Ms. Pek's onset was with a medically acceptable timeframe. I find that none of the *Althen* prongs have been satisfied.

First, Petitioner's theory, while it has reliable scientific/medical elements, has not been established preponderantly *overall*. As a threshold matter, I note that in prior cases I have generally observed a distinction between acute demyelinating injuries that cause sudden and abrupt injury to the CNS (e.g., TM), and those that are chronic, relapsing/remitting, and/or progressive, like MS. *Morgan v. Sec'y of Health & Human Servs.*, No. 15-1137V, 2019 WL 7498665, at *16 (Fed. Cl. Spec. Mstr. Dec. 4, 2019), *appeal docketed*, Mot. for Rev., filed Jan. 3, 2020 (ECF No. 65). While the former kind of injuries are often successfully established in the Program, and credibly so, the latter are not—whether with respect to the flu vaccine or the Tdap (a vaccine that has been recognized to be far less likely to cause injury than its prior iteration, DPT, which contained whole-cell pertussis).[20] *See Raymo v. Sec'y of Health & Human Servs.*, No. 11-654V, 2014 WL 1092274, at *23 (Fed. Cl. Spec. Mstr. Feb. 24, 2014) (finding causal relationship between flu vaccine and TM); *but see Wei-Ti Chen v. Sec'y of Health & Human Servs.*, No. 16-634V, 2019 WL 2121208, at *22 (Fed. Cl. Spec. Mstr. Apr. 19, 2019) (insufficient evidence was provided to support a causal connection between the flu vaccine and petitioner's subsequent development of neuromyelitis optica spectrum disorder, which is chronic and relapsing/remitting like MS). I have also yet to see, or preside over, a case in which a claimant successfully explained, through expert testimony or literature, how a purportedly vaccine-caused acute demyelinating event could evolve into a chronic condition (although it is wholly conceivable that this could be done).

As a result, Petitioner faced an uphill effort in establishing that *any* vaccine might initiate

[19] I note that neither party has objected to this matter being resolved through a ruling on the record. *See generally* Mot. (ECF No. 42); Opp. (ECF No. 45).

[20] *Sharpe v. Sec'y of Health & Human Servs.*, No. 14-065V, 2018 WL 7625360, at *31–32 (Fed. Cl. Spec. Mstr. Nov. 5, 2018) (discussing several cases in which it was found that the Tdap or DTaP vaccine is generally considered to be much less likely than DPT to cause neurologic reactions), *aff'd*, 142 Fed. Cl. 630 (2019), *appeal docketed*, May 31, 2019 (ECF No. 120).

a chronically-aberrant immune process over a lengthy time period resulting in an MS diagnosis. But measured simply on the basis of the literature offered in this case rather than the context of the claim, Petitioner's effort was wanting. Petitioner filed a large number of items of literature pertaining to proposed mechanisms, like molecular mimicry, relevant to autoimmunity—but little specific to MS as likely having molecular mimicry as its pathogenic driver. Cross-reactivity as a driver of certain kinds of autoimmunity is a reliable scientific concept, as far as it goes, but is more trustworthy in explaining *other* kinds of demyelinating injuries. *See, e.g.*, *Barone v. Sec'y of Health & Human Servs.*, No. 11-707V, 2014 WL 6834557, at *8–9 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (finding that the theory of molecular mimicry was a reliable medical theory for how the flu vaccine could cause GBS). Certainly nothing offered in this case was specific to MS's pathogenesis for either vaccine—whether alone or together as alleged.

Dr. Steinman was amply qualified to offer testimony on this topic, but his report was thinly supported in several respects.[21] Given the absence of direct evidence associating vaccination with MS, he relied on several Vaccine Program "old warhorses" to advance his theory. Thus, he brought out the notion of molecular mimicry to link the flu vaccine to MS, relying on what he has previously deemed (in other cases) an "in silica" (or desktop) experiment—establishing homology simply by looking up amino acid sequences in computer databases, rather than citing studies or experiments *demonstrating* that components of a vaccine do in fact have cross-reactive potential with self-protein structures. *See, e.g.*, *Blackburn v. Sec'y of Health & Human Servs.*, No. 10-410V, 2015 WL 425935, at *9–10 (Fed. Cl. Spec. Mstr. Jan. 9, 2015). But showing some amino acid sequence congruence does not by itself preponderantly establish that a specific vaccine component will more likely than not cause a cross reaction with a comparable self-structure. Indeed, homology between the amino acid chains of foreign antigens and self-structures can exist *without* pathology, let alone an autoimmune response. *Blackburn*, 2015 WL 425935, at *7 n.14 ("[t]hough homology is necessary to trigger molecular mimicry, Dr. Steinman conceded that the existence of homology alone does not lead automatically to the conclusion that molecular mimicry has or will occur.").

The secondary component of Dr. Steinman's theory—how alum in the Tdap vaccine would stimulate certain disease-encouraging cytokines, like IL-1β, that would further propagate an autoimmune disease process—was also evidentiarily deficient. Nothing he offered in support of this concept established that these cytokines are likely pathogenic at all; articles like Hauser (which stand as a fairly old item of literature in the first place) allow for the possibility that this cytokine could be the *result* of an ongoing autoimmune process rather than its driver, as Dr. Steinman's

[21] This is not a case in which I find that Petitioner's expert opinion on a causation subject was effectively rebutted by Respondent's expert. Although Dr. Donofrio credibly established that Petitioner most likely suffered from MS, the segments of his opinion addressing the capacity of the Tdap vaccine to cause MS were themselves thin. However, because Petitioner did not in the first instance offer sufficient preponderant evidence on the "can cause" *Althen* element, she did not prevail *even though* Respondent's counter-showing was itself not especially robust.

theory presumed. Hauser, *supra*, at 1737.[22] In addition, as I have observed in other cases, arguments about the disease-causing potential of adjuvants like alum attempt ultimately to turn on its head what is known about the immune-stimulative properties of adjuvants, and are thus more rooted more in conjecture than reliable science. *See, e.g.*, *Zumwalt v. Sec'y of Health & Human Servs.*, No. 16-994V, 2019 WL 1953739, at *18 (Fed. Cl. Spec. Mstr. Mar. 21, 2019), *mot. for rev. denied*, slip. op. at 25 __ Fed. Cl. __ (2019). He did not establish in more than a conclusory manner that the cross-reactive potential of flu vaccine components would be aided due to alleged upregulation of cytokines induced by a different, subsequent vaccine. Certainly, he offered no literature, and referenced no research of his own, establishing that an alum-containing vaccine could assist an ongoing autoimmune process, regardless of what instigated that process in the first place.

Again—some aspects of Dr. Steinman's theory had reliable scientific support, and certainly he was amply qualified to propose a causation theory given his expertise with CNS diseases and immunology. The idea that an exogenous stimulus, such as vaccination, might be sufficient to initiate an autoimmune process negatively impacting the CNS and thereby causing MS has some plausibility. But scientific plausibility does not amount to an evidentiarily-preponderant showing that the flu and/or Tdap vaccine could cause MS—a distinction the Federal Circuit has recognized. *See Canuto v. Sec'y of Health & Human Servs.*, 660 Fed. Appx. 955, 957 (Fed. Cir. 2016) (citing *W.C.*, 704 F.3d at 1356 ("the petitioner must do more than demonstrate a 'plausible' or 'possible' causal link between the vaccination and the injury; he must prove his case by a preponderance of the evidence.")). Absent some more compelling evidence and testimony centered on MS as opposed to other demyelinating illnesses about which more is known, or something explaining how vaccination could initiate *any* chronic demyelinating condition, I cannot find the first *Althen* prong has been satisfied.

Second, Petitioner has not established that the flu and Tdap vaccines together likely caused her MS. No treater proposed an association between these vaccines and Petitioner's injury (and indeed Petitioner's primary treater, Dr. Gunawardane, misapprehended the very nature of her illness, repeatedly deeming it GBS when the record hardly supports that diagnosis at all).[23] Petitioner also showed no sign before her early January 2015 onset that she might arguably be

[22] Dr. Steinman's theory also seems to assume that receipt of an alum-containing vaccine like Tdap (importantly, the flu vaccine administered in the U.S. is not adjuvanted) would cause migration of cytokines stimulated in the periphery to move into the CNS and cause harm—even though Hauser acknowledges that because it is unlikely they could breach the blood-brain barrier, those cytokines were likely produced from *within* the CNS. Hauser, *supra*, at 1737. But Petitioner's causation theory did not explain how stimulation from outside the CNS could cause upregulation of cytokines from within.

[23] There are other reasons to question the validity of aspects of Dr. Gunawardane's diagnoses. For example, the record reveals more than one instance where he deems the finding of oligoclonal bands in Petitioner's CSF as indicative of GBS (*see, e.g.*, Ex. 2 at 10, 33)—even though this CSF finding is most commonly associated with MS. McDonald Criteria, *supra*, at 296; Donofrio Rep. at 9.

experiencing an unfolding autoimmune process (which, for example, might be revealed in evidence of existing inflammation or some other symptom)—not in the nearly three months after she received the flu vaccine, or in the almost two months from the time she received the Tdap vaccine. On the contrary: the symptoms she was experiencing up to the date of onset were more consistent with her pre-vaccination problems, such as chiropractic treatment for her preexisting neck and back pain. And there is no testing result or other record element, beyond the fact of onset itself, to which Petitioner can point to as substantiating the role vaccines played in her injury, or that the receipt of the Tdap vaccine built on a pathologic process already underway from Petitioner's October 2014 flu vaccination.

Third, the timeframe in which Petitioner experienced MS onset post-vaccination has not been shown to be medically acceptable. To some extent, this conclusion flows from my determination that the vaccines at issue have not been demonstrated to be causal of MS in the joint manner proposed by Dr. Steinman—but even had I not found so, timing of onset based on the facts of this case would still defeat an entitlement finding. No overall persuasive explanation has been provided for why it would take a little less than two months from receipt of the Tdap vaccine for an individual like Ms. Pek to begin to experience MS symptoms (especially since MS can often be symptomatically silent for long periods of time—even when vaccination is not at issue). *See, e.g.*, *P.M. v. Sec'y of Health & Human Servs.*, No. 16-949V, 2019 WL 5608859, at *4 (Fed. Cl. Spec. Mstr. Sept. 24, 2019) (discussing radiologic isolated syndrome—a disorder in which a patient will be asymptomatic but exhibits CNS lesions on MRIs that may long predate their discovery). She also did not credibly explain how the impact of the flu vaccine prior to this time would temporally interact with cytokine stimulation encouraged by alum—other than to rely on things already known about cytokine production post-vaccination. She simply did not establish why the process resulting in her early-January symptoms would take nearly two months to manifest in injury.

Admittedly, to support the timing aspect of his opinion, Dr. Steinman offered one item of literature, Bielekova, that was itself scientifically reliable. Yet Bielekova is far less supportive of Petitioner's claim than Dr. Steinman acknowledges, and there are several sound reasons not to give it great weight (beyond the obvious fact that it says nothing about the timeframe in which a vaccination might result in demyelinating injury). The aspect of the study he cites for this proposition, for starters, involved only *three* patients, making it difficult to conclude that *overall* any molecular mimicry-driven process impacting CNS demyelination could potentially occur up to five weeks post-vaccination. Next, the article considered individuals who already had MS, and evaluated disease and immune cell response after introduction of the mimic—*not* instigation of the disease process at the outset. Most significantly, Bielekova's subjects were receiving doses of the immune-stimulating mimic antigen (the association of which to MBP and the disease processes of MS was far better known than the flu or Tdap vaccines) on a *weekly or monthly basis* during the observed period—hardly comparable to the purported subsequent effect of a one-time receipt of a vaccine. This article is therefore fairly weak support for Dr. Steinman's contention that the

timeframe for Petitioner's post-vaccine onset was medically acceptable.

II. This Matter was Properly Resolved Without Hearing

In ruling on the record, I am opting against holding a hearing. The choice of how best to resolve this case is a matter that lies generally within my discretion, and neither party appears to question this choice, but I shall explain my reasoning nevertheless.

Prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to "afford[] each party a full and fair opportunity to present its case." *Hovey*, 38 Fed. Cl. at 400–01 (citing Rule 3(b)). But that rule also includes the obligation of creation of a record "sufficient to allow review of the special master's decision." *Id*. Thus, the fact that a claim is legitimately disputed, such that the special master must exercise his intellectual faculties in order to decide a matter, is not itself grounds for a trial (for if it were, trials would be required in every disputed case). Special masters are expressly empowered to resolve fact disputes *without* a hearing—although they should only so act if a party has been given the proper "full and fair" chance to prove their claim.

In this case, no hearing was required to resolve fairly Petitioner's claim. The assertion that a vaccine can cause MS is not unheard-of in the Program, and is a matter I have been asked to evaluate on several prior occasions. I have also had the opportunity to hear live the testimony of both sides' experts (at least once in the *same* case),[24] and am very familiar with their credentials and bona fides, as well as the opinions they often give. I was able to evaluate the evidentiary strength of their theories and opinions simply based on the expert report filings, and did not require credibility determinations in weighing the medical/scientific reliability of the theories espoused. The case did not otherwise turn on any fact issues (for example, the ultimate diagnosis or onset) that would have merited allowing live testimony. Petitioner had a full and fair opportunity to present her claim without a live hearing.

CONCLUSION

The Vaccine Act permits me to award compensation to a petitioner alleging a "non-Table Injury" only if she can show by medical records or competent medical opinion that the injury was more likely that not vaccine-caused. Here, Petitioner's claim depends on my finding that her two to three-month post-vaccination onset of MS could be, and was, vaccine-caused, but the weight of the evidence does not support that conclusion. Thus, there is insufficient evidence to support an award of compensation, leaving me no choice but to hereby **DENY** this claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of Court),

[24] *See Chinea v. Sec'y of Health & Human Servs.*, No. 15-095V, 2019 WL 1873322 (Fed. Cl. Spec. Mstr. Mar. 15, 2019), *mot. for rev. denied*, 144 Fed. Cl. 378 (2019).

the Clerk shall enter judgment in accord with this decision. [25]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[25] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.